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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/776,687

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Gregory B. Altshuler

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05/24/2006

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EXAMINER

JOHNSON III, HENRY M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/776,687

Applicant(s)

ALTSHULER ET AL.

Examiner

Henry M. Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16, 18-20, 22-24, 26 and 28-39 is/are rejected.
- 7) ☒ Claim(s) 15, 17, 21, 25 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>020306</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

Applicant's arguments with respect to claims 5 and 6 have been considered but are moot in view of the new ground(s) of rejection to Azar et al.

Applicant's arguments filed 4/7/2006, with respect to claim 17 have been fully considered and are persuasive. The rejection has been withdrawn.

Applicant's arguments filed 4/7/2006 have been fully considered but, except as above, they are not persuasive.

Claim 1 requires a device sized to fit partially in a mouth and a radiation emitter. Any emitter in a mouth, unless specifically structured to restrict radiation, is capable of radiating facial tissue. No unique structure for such radiation emitter is cited. The claim does not specifically require the facial radiation be done from within the oral cavity. Whether a device radiates from within or outside the mouth is not dependent on its structure.

Interpretation of prior art on an apparatus claim is based on structure and capabilities. A disclosed intended use of prior art does not preclude additional uses.

Regarding claim 16, the bristles of Muller have a shape and clearly transmit radiation for the device to function.

Motivation to combine may have its genesis in any of the prior art teachings. Thus, the teaching of Altshuler et al. about the benefits of total internal reflection is sufficient motivation to combine with Muller. The analogous art is that of phototherapy, and a skilled artisan would look to such art for guidance.

The provisional obvious double patenting rejection have been tentatively withdrawn pending further evaluation as the claims in the co-pending applications are modified.

Specification

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The disclosure is objected to because of the following informalities:

In paragraph 01, full continuity data is required including application number, filing date and patent number (or other status; i.e. now abandoned).

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 7-9, 28-35, 38 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/06456 to Chen et al. Chen et al. teach an apparatus employing light therapy to treat oral conditions (abstract) including a mouthpiece that surrounds the teeth and gums (Fig. 2) that may be comfortably left inside a patient's mouth for extended times (page 2, lines 32-35) and is made from an elastomeric material such as silicone (page 5, line 8). This is interpreted as a compliant mouthpiece. The radiation source is disclosed as an LED, laser diode, gas discharge lamp or filament bulb (page 3, lines 30-32). The source may be mounted on the mouthpiece or located external to the mouthpiece with the radiation delivered via fiber optics (optical element). The means for delivery may include diffusing material (page 3, line 25). The optical fibers deliver the radiation in different directions (page 6, lines 13-15). Portions of

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the mouthpiece may be highly reflective (page 7, line 21). The sources mounted around the mouthpiece clearly radiate in different directions. Chen et al. incorporates by reference U.S. Patent 5,445,608 (also Chen et al.) that teaches the use of either an internal or external array of light sources and allows use of LEDs or laser diodes operating at two or more wavelengths, and the ability to selectively activate the sources operating at a given wavelength or waveband as desired, so that the light at the different wavelengths or wavebands is provided to the treatment site either sequentially or simultaneously from the light sources (Col. 8, lines 37-45). The sources may be controlled by monitoring the temperature rise of the tissue (diagnostic sensor) (Col. 8, line 8). The current regulation will control the power of the light source. In addition to multiple wavelengths, Chen et al. '608 further teaches other aspects of phototherapy. The delivery of a photosensitizer directly to the treatment area via a port in the apparatus and the apparatus adapted to use heat from the radiation source to heat the treatment area.

Regarding claim 9, the device is capable of radiating areas other than the teeth and gums.

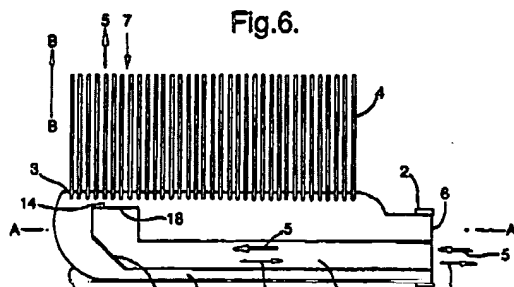
Regarding claim 29, Chen et al. '608 teaches diffusing the radiation with a semi-transparent polymer (Col. 11, lines 45-50).

Regarding claim 30, Chen et al. '608 teaches that light distribution to the treatment site can be effected at the distal end of the catheter by removing the coating of material over the desired output region of the catheter, and/or by abrasively roughening the exterior surface of the light guiding catheter (Col. 20, lines 15-30). In this case, the exterior is a cladding and the abrasive process is etching the cladding.

Claims 1, 4, 7-12, 14, 16, 18-19, 23 and 37 are rejected under 35 U.S.C. 102(e) as being

anticipated by U.S. Patent 6,862,771 to Muller.

Muller teaches a toothbrush with a head with



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bristles and a radiation source in a handle. The location in the handle is disclosed as convenient if the toothbrush is an electrical toothbrush, i.e. having electrical drive means to move the cleaning bristles in a tooth cleaning operation. The electric drive is interpreted as a vibrating mechanism. The radiation is directed in a direction parallel to the bristles either between the bristles or through the optically transparent bristles, thus teaching a plurality of emitters (Fig. 6). The bristles are interpreted as optical elements and capable of radiating in multiple directions as they are deflected during brushing. A reflecting surface directs the radiation to the bristles (Fig. 6, # 17). Along with the radiation source in the handle, a detector is disclosed for sensing reflected radiation. This detector is interpreted as a diagnostic sensor (Col. 2, lines 38-65). The apparatus is clearly **capable** of radiating any area within an oral cavity. The radiation source may be a light emitting diode (LED) of known type and filters and mirrors are disclosed in the optical path. The detection means and an appropriate power supply, electronic processing devices (control), and means to signal the presence and/or absence of biological deposits on a tooth surface may conveniently be provided within the handle of the toothbrush (Col. 8, lines 35-50). A lens may be used in the optical path (Col. 12, line 38) and this is interpreted as a diffuser as lenses may diverge a beam, effectively diffusing the beam. The bristles have a core made of a transparent plastic material, surrounded by a sheath also of a transparent plastic material with a lower refractive index than that of the core. Alternatively the sheath may be thin coating of a shiny metal, e.g. 2-3 microns thick (col. 13, lines 12-17). The head is disclosed as being detachable (Col. 8, line 55).

Regarding claim 16, Muller teaches radiation via the bristles inherently teaching their shape is appropriate and that they are lasing elements.

Claims 1, 10-14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,239,442 to Iimura. Iimura discloses a light emitting cleaning tool that may be made

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very small (Col. 7, line 45). The background discloses toothbrushes for cleaning, implying the tool can at least partially fit in a mouth. Particles to scatter and diffuse the radiation are disclosed (Col. 5, lines 33-37) and the bristles are disclosed as having a light reflecting means (claim 7). The bristles have a shape and radiate so the shape inherently allows radiation.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication US 2001/0024777 to Azar et al. Azar et al. disclose a device for oral hygiene that directs light toward a brushing head, the light may be provided by a gas discharge lamp or flashlamp (paragraph 0041). Filters are provided to determine the wavelength of emitted radiation (Fig. 3, #s 21 & 23).

Claims 1, 22, 24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,572,637 to Yamazaki et al. Yamazaki et al. teach a handheld light treatment device with a cylindrical adjuster (Fig. 2, # 20) to delivery the radiation to an area. The adjuster is interpreted as being capable of insertion into a mouth. The adjuster may be equipped with an extra microswitch responsive to adjuster's touching the skin for making the electric power supply to turn on, and responsive to adjuster's leaving the skin for making the electric power supply to turn off (Col. 3, lines 23-30). The radiation source is cooled by a heat sink (Fig. 2, # 18) and a fan is provided in the handheld unit (Fig. 2, # 14). Since the cooling means are all within the handheld unit, it is inherent the handle receives some of the heat.

Claims 1, 36 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,443,978 to Zharov. Zharov teaches a photomatrix device for irradiation of tissue using multiple LEDs that may be of different wavelengths (Col. 12, lines 1-5). A configuration is disclosed for use in a mouth (Col. 12, line 41). The device may include an ultrasonic module (Claim 61), the ultrasonic also interpreted as a vibrating element.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,862,771 to Muller as applied to claim 19 above and further in view of U.S. Patent 6,273,884 to Altshuler et al. Muller is discussed above, but does not disclose inhibiting radiation when not in contact with tissue. Altshuler et al. teach a tissue treatment apparatus and the concept of total internal reflection. The optical delivery channel is treated to normally have total internal reflection so that light or other radiation entering the channel is reflected internally, however, when lens (output face) is in contact with a patient's skin, the total internal reflection at the skin-contacting surface is broken due to the change of index of refraction at this surface so that light energy is emitted into the patient's skin (Col. 16, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the technique of modifying the index of refraction of the light channel as taught by Altshuler et al. in the invention

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of Muller to limit the radiation to the oral cavity as a safety consideration as suggested by Altshuler et al.

Allowable Subject Matter

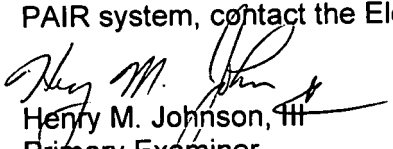
Claims 15, 17, 21, 25 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Henry M. Johnson, III
Primary Examiner
Art Unit 3739